

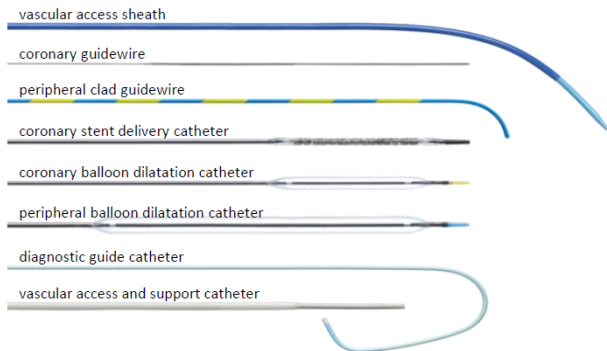
# SURMODICS™ *IN VITRO* DIAGNOSTICS

Amp Up The Signal, Dial Down the Noise



# SURMODICS CORE BUSINESS

## MEDICAL DEVICE COATINGS



Leveraging science and expertise to offer world-class coatings and drug delivery

## IN VITRO DIAGNOSTICS



Providing critical components for in vitro diagnostic tests and microarrays

## WHO WE ARE:

Publicly traded medical company established in 1979, located in Eden Prairie, Minnesota.

## MISSION:

To improve the detection and treatment of disease by using our technology to provide solutions to difficult medical device and diagnostic challenges.

# IN VITRO DIAGNOSTIC BUSINESS

We are a **leading provider** of chemical reagents for in-vitro diagnostic (IVD) tests and surface coatings.

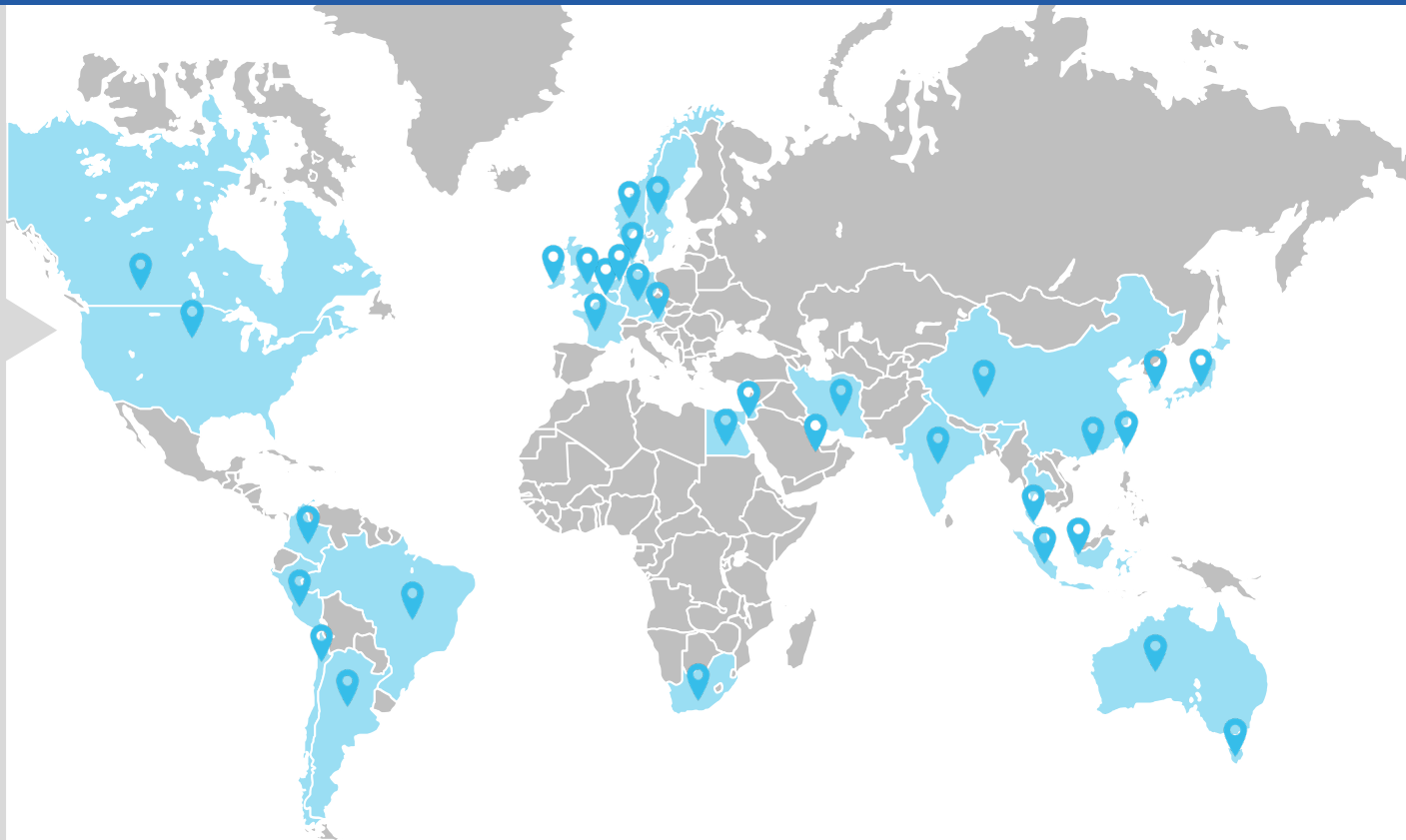
- 40 years of adding value by continually providing solutions to IVD kit manufacturers
- Our **broad portfolio** of proven immunoassay and point-of-care (POC) solutions improve the performance of a wide range of diagnostic tests
- Over 1,000 customers worldwide use Surmodics reagents



# ESTABLISHED IN WORLDWIDE MARKETS

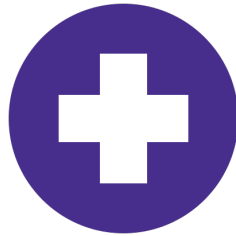
**Surmodics** reagents are critical components in hundreds of approved tests throughout the world

AUSTRALIA	ISRAEL
AUSTRIA	ITALY
ARGENTINA	JAPAN
BELGIUM	NETHERLANDS
BRAZIL	NEW ZEALAND
CANADA	NORWAY
CHILE	PERU
CHINA	SINGAPORE
COLOMBIA	SOUTH AFRICA
DENMARK	SOUTH KOREA
EGYPT	SWEDEN
FRANCE	SWITZERLAND
GERMANY	TAIWAN
HONG KONG	THAILAND
INDIA	UNITED ARAB EMIRATES
INDONESIA	UNITED KINGDOM
IRAN	UNITED STATES
IRELAND	



# IVD MARKET SEGMENTS

**Surmodics IVD** is a leading provider of broad array chemical reagents for *in vitro* diagnostic assays and surface coatings for a variety of markets



CLINICAL  
DIAGNOSTICS



VETERINARY



DOMESTIC &  
INTERNATIONAL



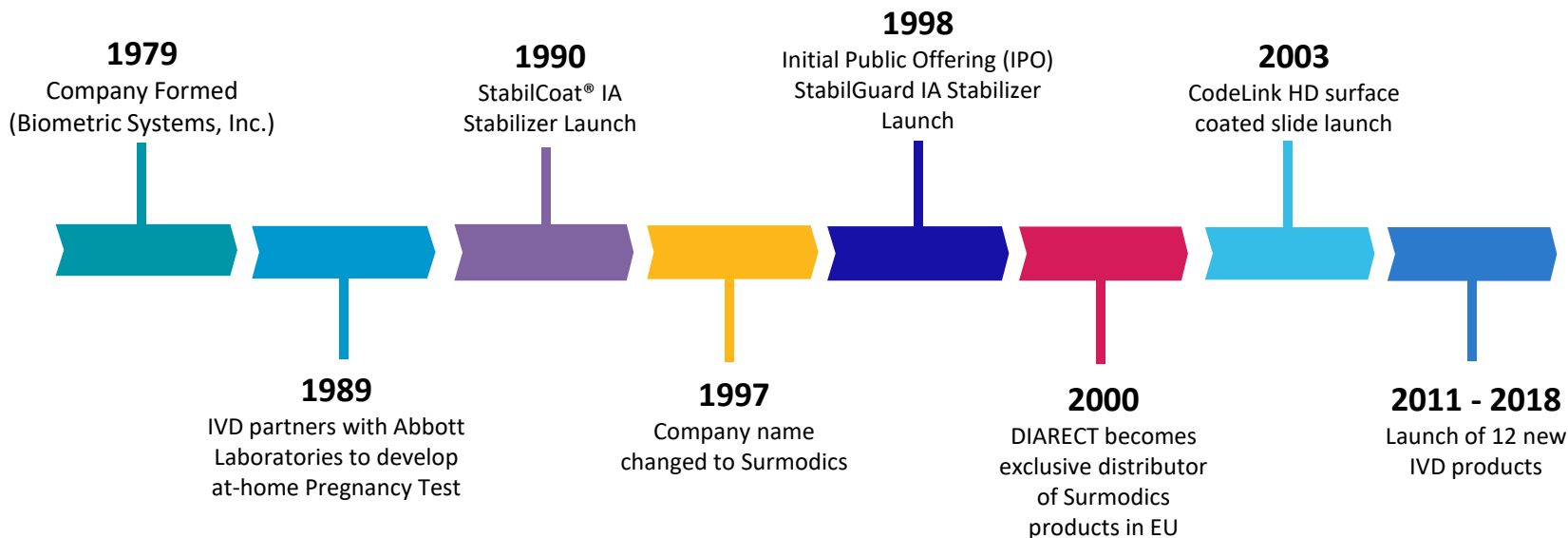
AGRICULTURE



RESEARCH



# COMPANY MILESTONES

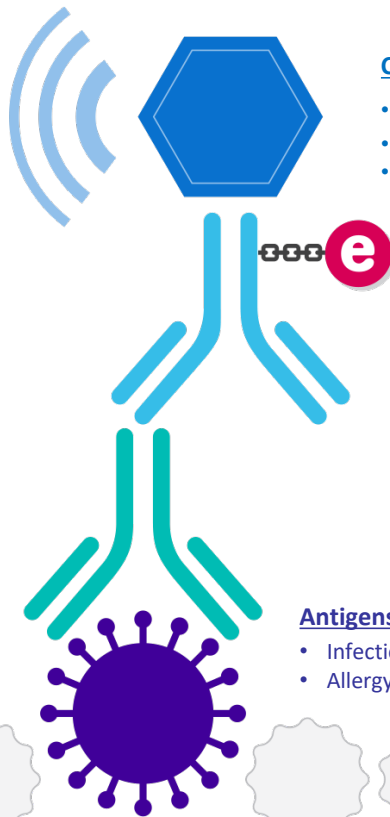


# HISTORY OF INNOVATION

## Stop Solutions

- Nova-Stop Solution
- Nova-Stop 5X Solution

YIELDS  
COLOR  
SIGNAL



## Colorimetric Substrates

- Extended Shelf Life ABTS Substrate
- TMB Extended Range HRP Microwell Substrate
- TMB Enhanced HRP Membrane Substrate

## Conjugate Stabilizers

- StabilZyme® AP Protein-Free Stabilizer
- StabilZyme® Protein-Free Stabilizer
- Stabilizers with alternative biocides for EU

## Sample/Assay Diluents

- MatrixGuard™ Diluent
- Assay Diluent (Protein-Free)

## Antigens

- Infectious Disease Antigens
- Allergy Antigens






## Dried Protein Stabilizers

- StabilBlock®  
Immunoassay Stabilizer

# IVD DIAGNOSTICS

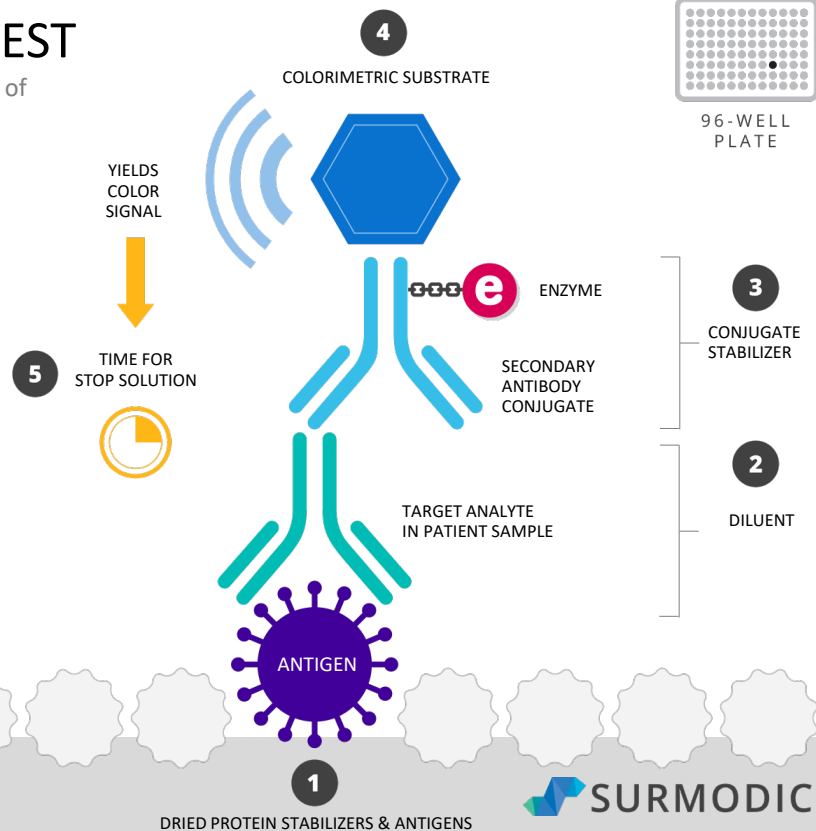
Surmodics IVD products offer differentiated levels of performance to ensure accurate diagnosis based on the absence or presence of disease

## COMPONENTS

-  **Dried Protein Stabilizer & Antigen** – Microwell plates are prepared with antigens/primary antibodies, blockers and stabilizers
-  **Diluent** – Target analyte (patient sample) is added and assay diluent/HAMA blocker is applied.
-  **Liquid Protein Stabilizer** – Secondary antibody conjugate (with enzyme) is added along with conjugate stabilizer
-  **Colorimetric Substrate** – Applied to yield a color signal related to diagnosis (presence or no presence of disease)
-  **Stop Solution** – Once color signal is achieved, a stop solution is applied to maintain color and discontinue further reaction

## ELISA TEST

Close-up View of Single Well





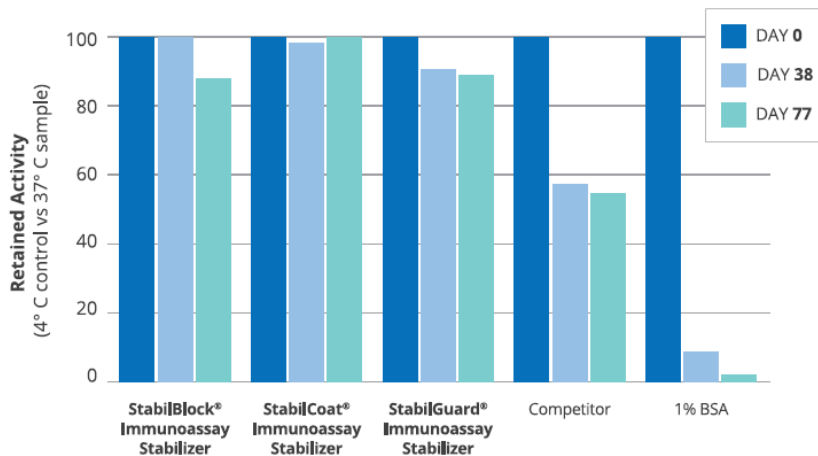
# DRIED PROTEIN STABILIZERS: STABILITY PERFORMANCE

Surmodics *StabilBlock*<sup>®</sup>, *StabilGuard*<sup>®</sup> and *StabilCoat*<sup>®</sup>

formulations retain protein activity while simultaneously blocking non-specific (unwanted) protein interactions.

- 85% retained activity for over 2 years
- Elimination of protein interference & cross reactivity
- Various blocking capacities to match the assay requirements.
- 1-step application process

## DRIED PROTEIN STABILITY



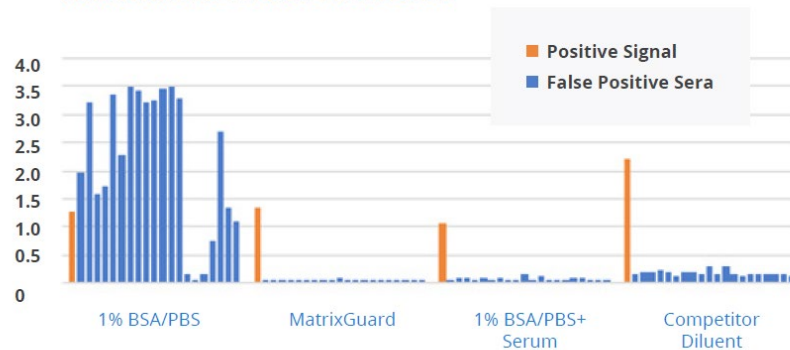
# MatrixGuard Diluent Performance

## Unsurpassed Signal Performance

MatrixGuard Diluent outperforms the competition in maintaining a strong positive signal, while simultaneously reducing false positive sera

**Figure:** Pappalysin 1 assay was run with twenty serum samples that displayed false positive signals. Fifty microliters of serum or positive samples were added to 100 uL of each assay diluent during the sample incubation step.

### MAINTAINING SIGNAL INTEGRITY



DILUENT

# LIQUID PROTEIN STABILIZERS: HRP PERFORMANCE

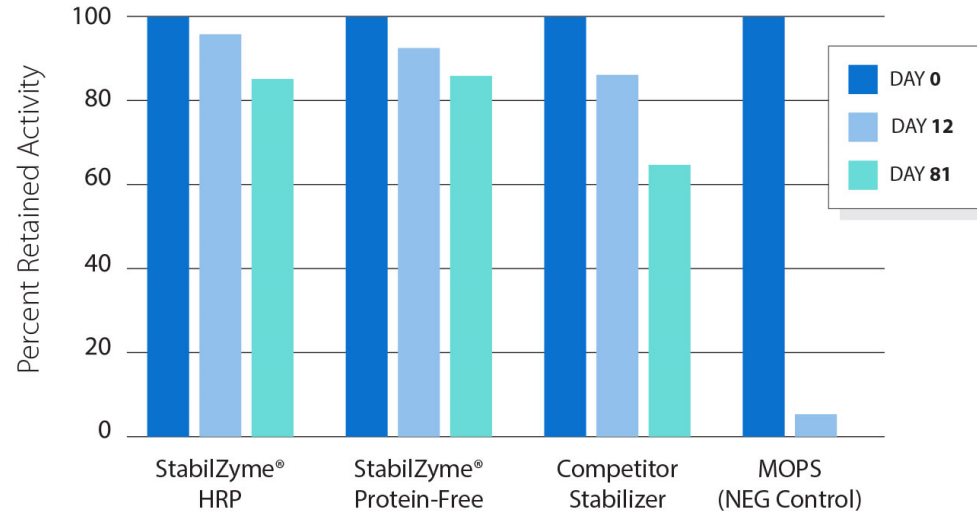
## Unparalleled Long-Term Stability

The Surmodics StabilZyme® family provides unparalleled long-term stability of protein conjugates at working strength concentrations for immunoassay development. Our formulations for HRP conjugates, AP conjugates and general protein applications ensure that assay developers have a complete set of tools to address the labile nature of each protein of interest.

- 85% retained activity for over 2 years
- Outperforms competitive products over the long term

**Figure:** A diluted HRP-conjugated antibody was stored at 37°C for 81 days and compared to a 4°C control

## OUTSTANDING RETAINED ACTIVITY



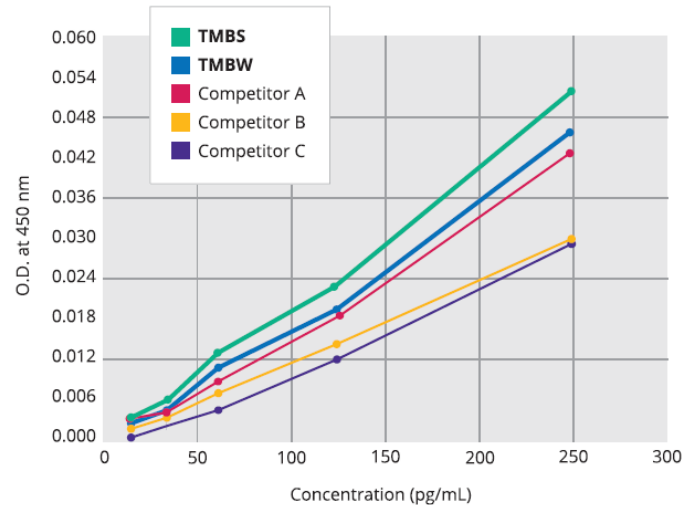
# BIOFX<sup>®</sup> TMB HRP COLORIMETRIC SUBSTRATES: SENSITIVITY

**Boosting signal strength.** For increased sensitivity, BioFX<sup>®</sup> TMB substrates generate higher signal per picogram of HRP faster than other TMB substrates.

Graph Details:

**Boosting signal strength.** For increased sensitivity, BioFX<sup>®</sup> TMB substrates generate higher signal per picogram of HRP faster than other TMB substrates. An HRP standard was serially diluted to 256, 128, 64, 32 and 16 pg/mL concentrations. The serial dilutions were added to a rabbit anti-HRP antibody coated microplate, incubated and washed. Each manufacturer's TMB was run in triplicate for each serial dilution, incubated for 10 minutes and stopped. Absorbance was read at 450 nm.

## SENSITIVITY

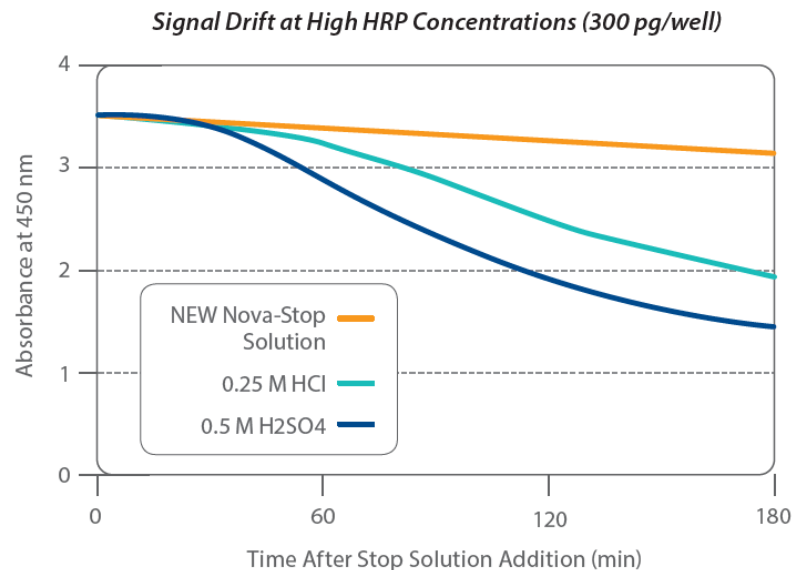


COLORIMETRIC SUBSTRATES

# STOP SOLUTIONS

Surmodics proprietary *BioFX*<sup>®</sup> stop solutions are available as dry blends or in liquid formulations and provide minimal signal drift at high or low concentrations

- New *BioFX*<sup>®</sup> Liquid Nova-Stop Solution
- Stable for 48 months at room temperature
- Non-corrosive to skin and eyes
- Greater consistency between plates and wells



# COMPETITIVE ADVANTAGES

Surmodics is the full solutions provider to the in-vitro diagnostics manufacturer.

- **Gold standard product performance** within the industry
- **Improves assay manufacturing processes** and overall quality
- **Strong technical expertise** for consulting on assay development
- **Quality is a way of life** (ISO 13485:2016 and 9001:2015 certified)



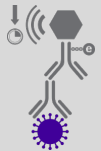
# ADDITIONAL DATA



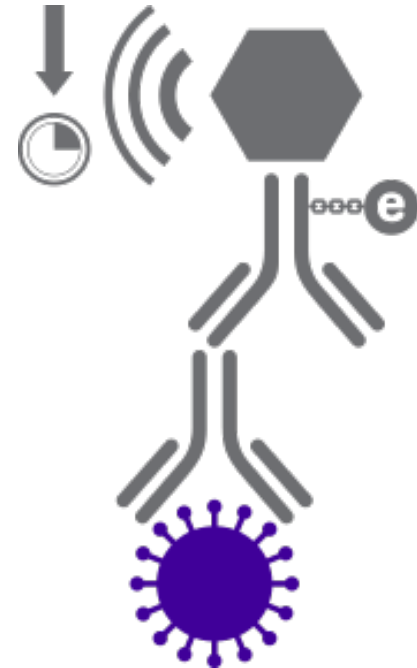
# DIARECT ANTIGENS

**DIARECT antigens** have a proven reputation for quality and sensitivity in ELISA and blotting applications

- Gold Standard manufacturer of autoimmunity, infectious disease & allergy antigens.
  - Superior purity of recombinant and native proteins for autoimmune diseases
  - Most complete line of autoantigens in the industry
- ISO 13485:2016 and 9001:2015 registered facilities
- Bulk manufacturing capabilities in Baculovirus & E. coli expression systems



ANTIGENS



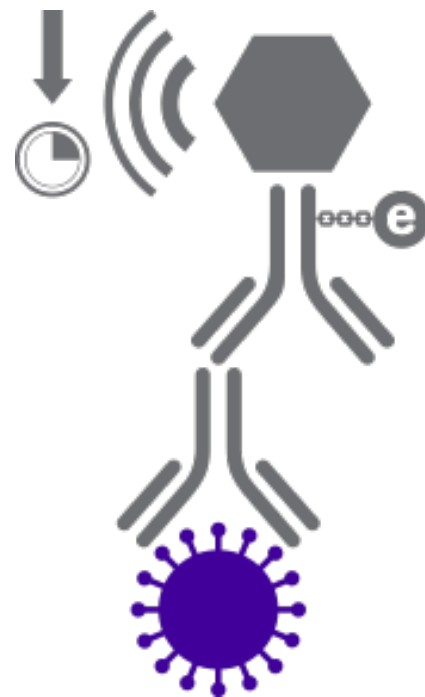


# DRIED PROTEIN STABILIZATION

ELISA manufacturers require effective blocking and stability for long term storage of antibody/antigen coated surfaces. Surmodics' **Immunoassay Stabilizers** provide:

**Immunoassay Stabilizers** provide:

- Unsurpassed dried protein stability for extended shelf life of ELISA assays.
- Blocking efficacy: low backgrounds & excellent signal-to-noise ratios across the assay range
- Inert blockers eliminate non-specific binding
- Ease of manufacturing



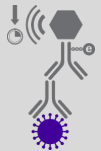
DRIED PROTEIN STABILIZERS

# DRIED PROTEIN STABILIZERS: SIGNAL-TO-NOISE & NON-SPECIFIC BINDING PERFORMANCE

Surmodics *StabilBlock*<sup>®</sup>, *StabilGuard*<sup>®</sup> and *StabilCoat*<sup>®</sup>

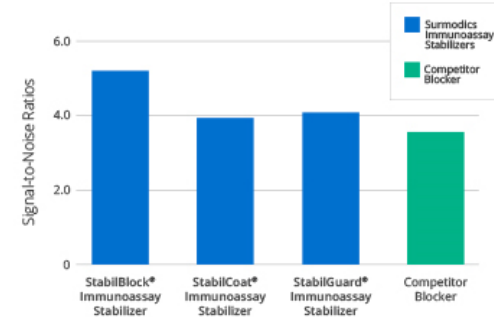
formulations retain protein activity while simultaneously blocking non-specific (unwanted) protein interactions.

- Multiple blocking options for optimal Signal-to-Noise ratios in each assay
- Lower non-specific binding from the sample matrix & downstream assay components
- Enabling lower detection limits

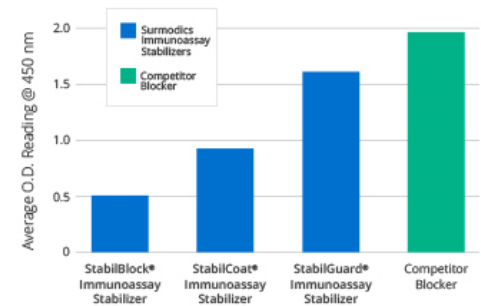


DRIED PROTEIN STABILIZERS

## SIGNAL-TO-NOISE RATIOS



## NON-SPECIFIC BINDING

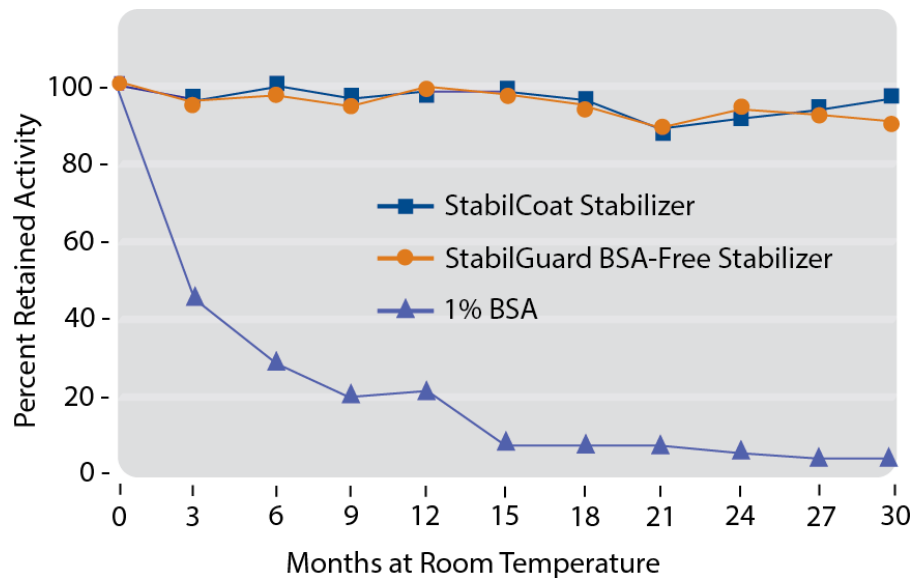


# DRIED PROTEIN STABILIZERS: PERFORMANCE

Surmodics *StabilGuard*<sup>®</sup> and *StabilCoat*<sup>®</sup> formulations retain protein activity while simultaneously blocking non-specific (unwanted) protein interactions.

- 95% retained activity over 30 months.
- Elimination of protein interference & cross reactivity
- Various blocking capacities to match the assay requirements.
- 1-step application process

## Real-Time Stability Testing



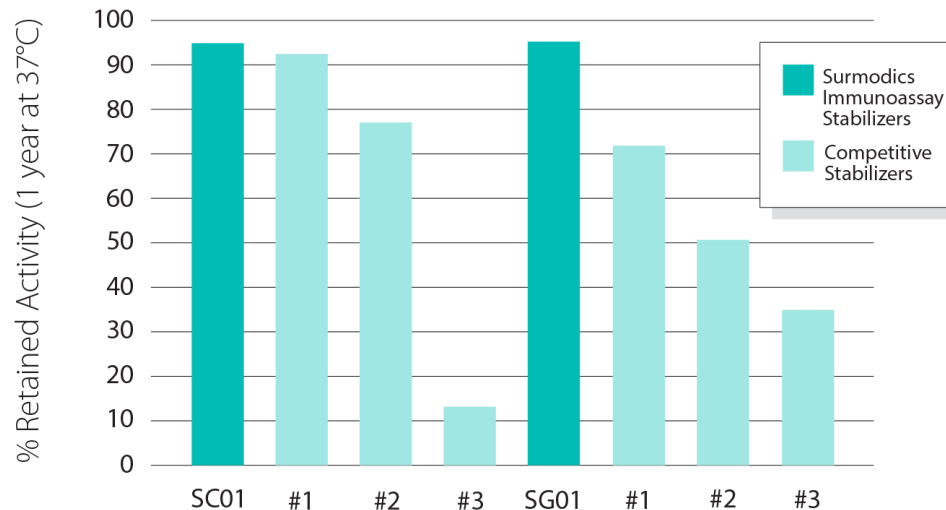
# DRIED PROTEIN STABILIZERS: COMPETITOR COMPARISON

- The **StabilGuard®** & **StabilCoat®** have superior stability than other commercial products.
  - 95% retained activity for over 1 year of a labile protein
  - Outperforms competitive products over the long term
  - Multiple blocking strengths to achieve the desired blocking efficacy
  - A one-component blocking/stabilizing process to streamline the manufacturing process of ELISA kits



DRIED PROTEIN STABILIZERS

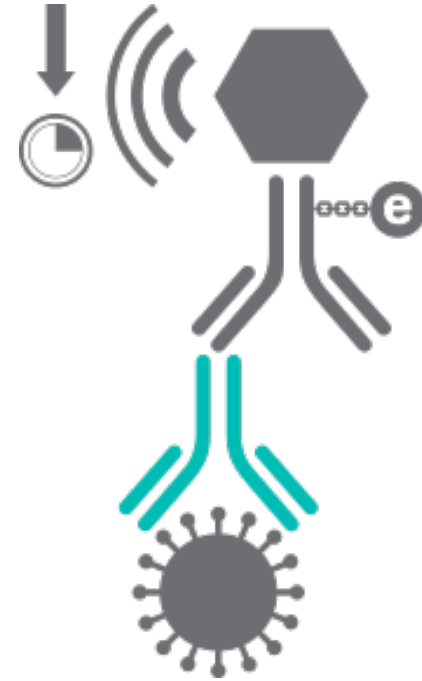
## RETAINED ACTIVITY AT ONE YEAR



# DILUENTS

Developing an ELISA requires the normalization of the sample matrix and reduction of interferences to be built within the assay design. Surmodics® Assay Diluent (Protein-Free) and MatrixGuard™ Diluent offer:

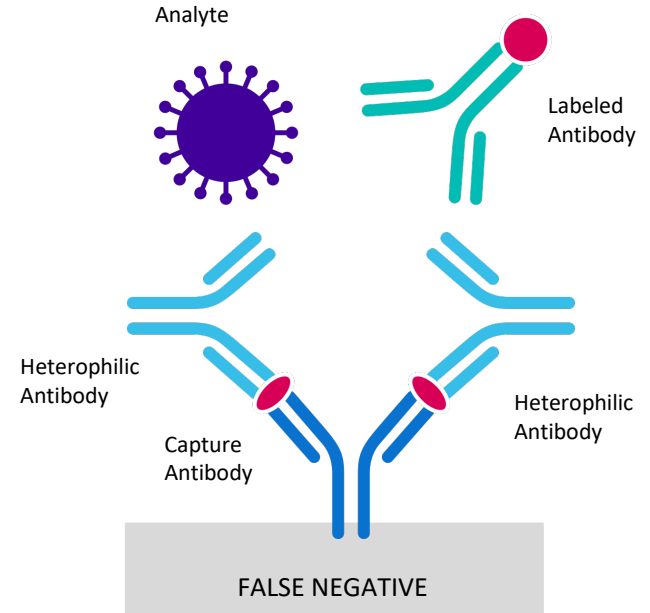
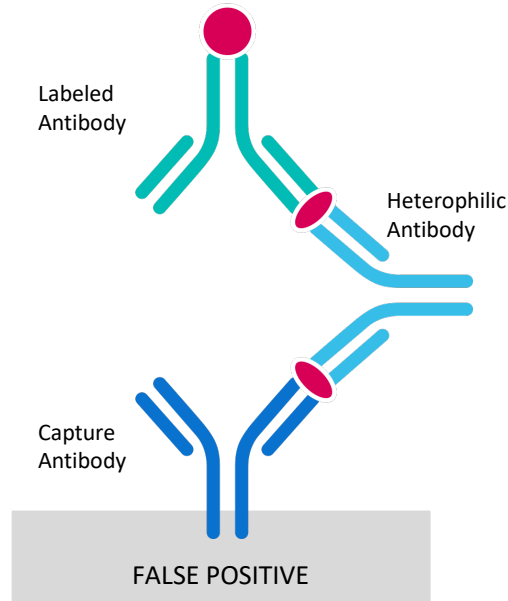
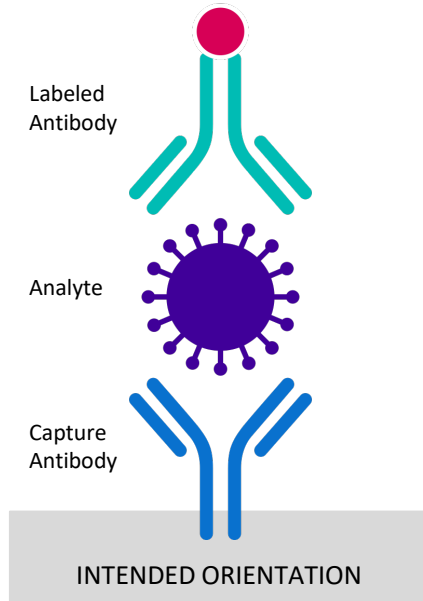
- Blocking of interferences (Heterophilic antibodies, HAMA, Rheumatoid Factor)
- Reduction of matrix interferences and the risk for false positives across multiple assay formats
- Maintains signal-to-noise ratios
- Ensures linearity and spike recovery



DILUENT

# SURMODICS DILUENTS

## Sandwich Assay Interference Mechanism

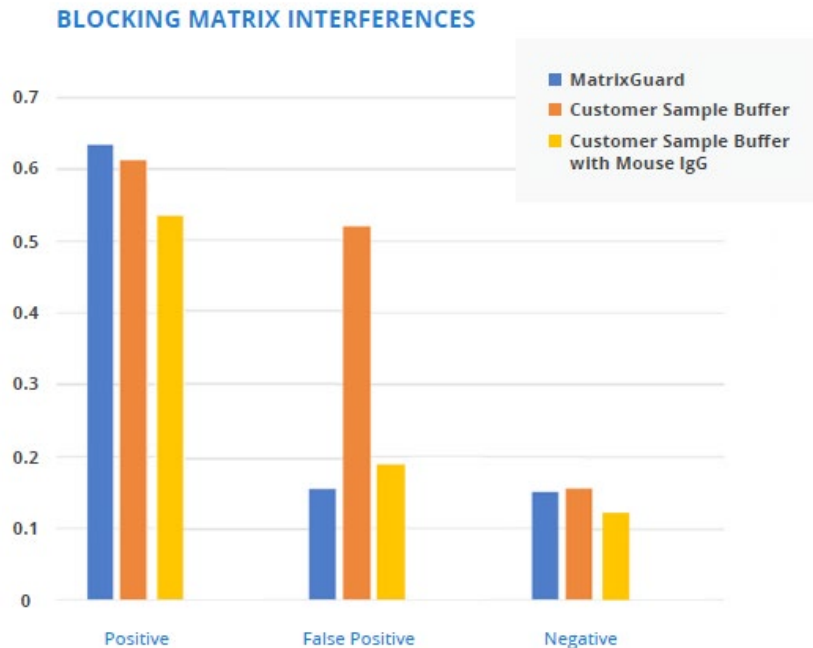


DILUENT

# MatrixGuard Diluent Customer Performance

## Outstanding Reduction of False Positives

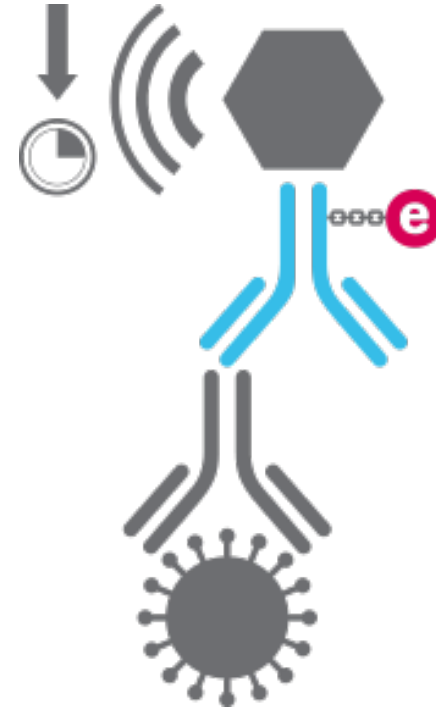
Figure: 50 ul buffer (as defined on the graph) containing the customer's detection antibody was added to the wells of antibody coated 96 well plate. Immediately 100 ul of sample (Positive, False Positive, Negative) was added to each well and incubated for 1 hour. The plate was then washed, Streptavidin-HRP was added to each well for color development. The graph shows the OD 650 recorded for each sample and buffer combination.



# LIQUID PROTEIN STABILIZERS

ELISA manufacturers require long-term stability of in-solution proteins to meet the shelf life requirements of clinical diagnostics laboratories. The gold standard **StabilZyme®** conjugate stabilizers offer:

- Unsurpassed in-solution stability of protein & enzyme conjugates
- Enables storage of conjugated proteins at lower use concentrations
- Lot-to-lot consistency



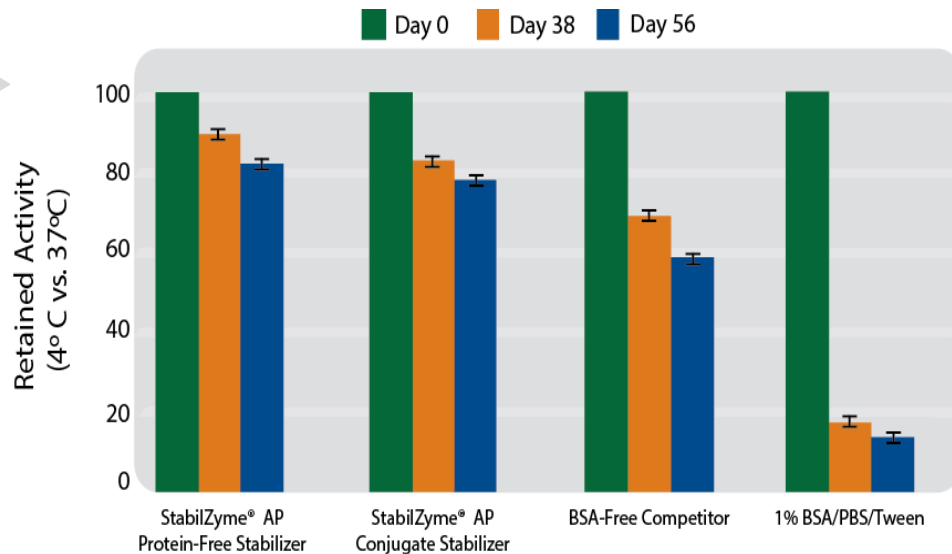


# LIQUID PROTEIN STABILIZERS: AP PERFORMANCE

**StabilZyme® AP & StabilZyme® AP Protein-Free** stabilizers are the gold standard in the IVD industry.

- 80% retained activity using accelerated stability testing
- Outperforms competitive products over the long term

**Figure:** A diluted AP-conjugated antibody was stored at 37°C for 56 days.



LIQUID PROTEIN STABILIZERS

# BIOFX<sup>®</sup> SUBSTRATES

Surmodics offers a full portfolio of substrates to satisfy every need of an IVD kit manufacturer. The main selection criteria are:

- Sensitivity
- Stability
- Low backgrounds
- Lot-to-lot consistency

## Horseradish

Alkaline

TMB

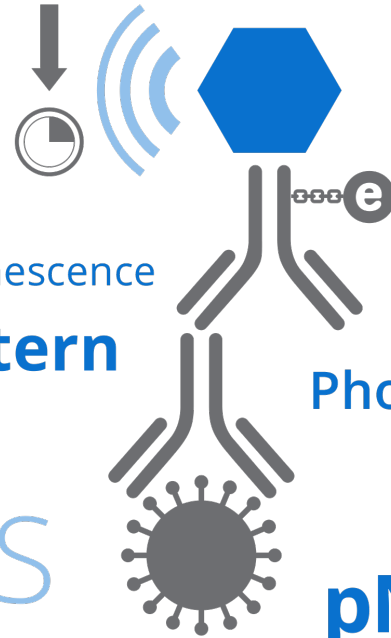
Chemiluminescence

Western

Blotting

ABTS

Peroxidase



Western

ELISA

IHC

BCIP-NBT

Phosphatase

DAB

pNPP

 SURMODICS



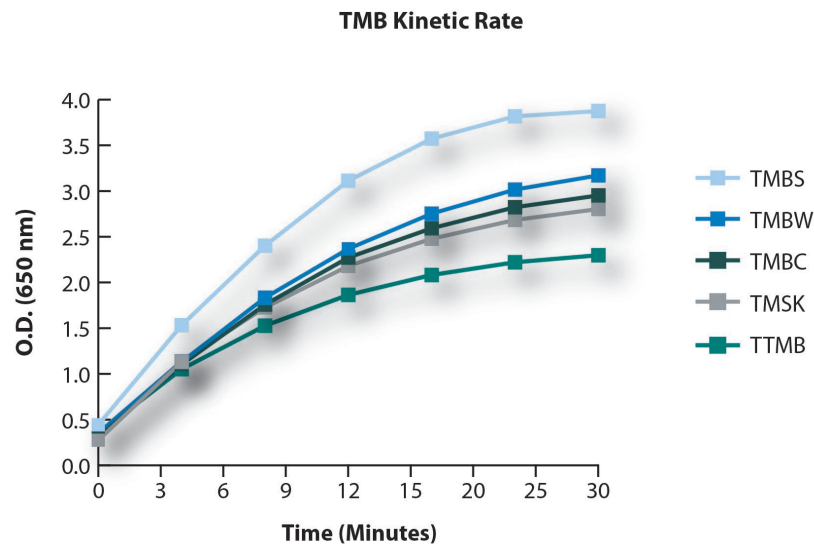
SUBSTRATES

# BIOFX<sup>®</sup> TMB HRP COLORIMETRIC SUBSTRATES: SENSITIVITY

The right substrate can make a substantial contribution to the overall sensitivity of an assay. The **BioFX<sup>®</sup>** TMB family offers:

- ↑ Signal-to-Noise ratios
- Detection limits in the low picogram/mL range
- Multiple substrates with different kinetic rates to meet assay specific requirements

**Figure:** Surmodics *BioFX<sup>®</sup>* Super Sensitive TMB has the fastest overall enzyme kinetics for rapid color formation and improved assay sensitivity and performance



COLORIMETRIC SUBSTRATES

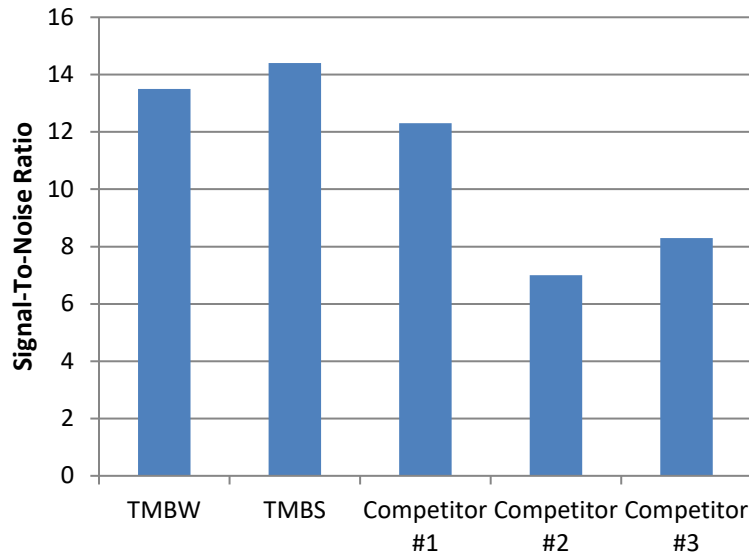
# BIOFX<sup>®</sup> TMB HRP COLORIMETRIC SUBSTRATES: LOW BACKGROUNDS

A substrate needs to provide maximum sensitivity with the lowest backgrounds possible.

BioFX<sup>®</sup> substrates offer:

- Low backgrounds across all kinetic rates
- Maximum signal-to-noise ratios without introducing error due to high backgrounds

## Competitive Set Signal-to-Noise Ratios: 3.0 ng/mL sample

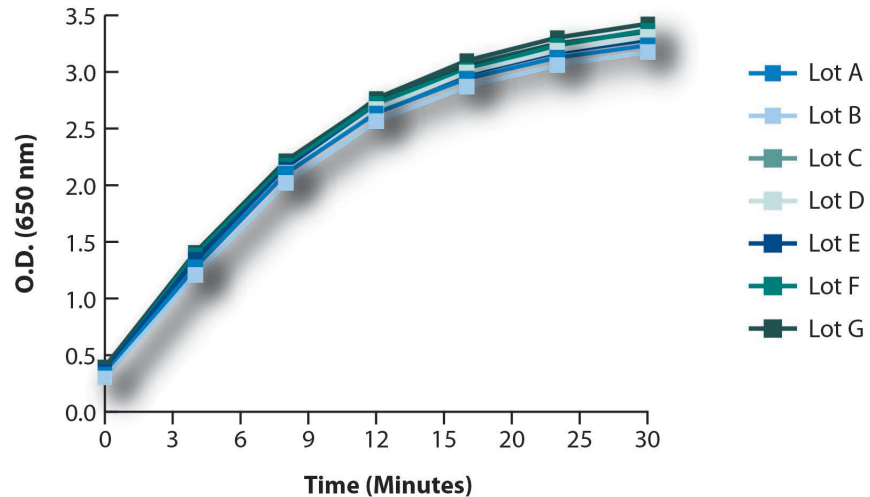


# BIOFX<sup>®</sup> TMB HRP COLORIMETRIC SUBSTRATES: CONSISTENCY

Surmodics *BioFX*<sup>®</sup> TMB Substrates are produced in an ISO 13485/9001 manufacturing facility to provide lot-to-lot consistency

- Less than 5% variation between lots is able to be realized
- Key benefit is lower variability in the ELISA manufacturing process and assay performance

TMB Kinetic Lot-to-Lot Consistency



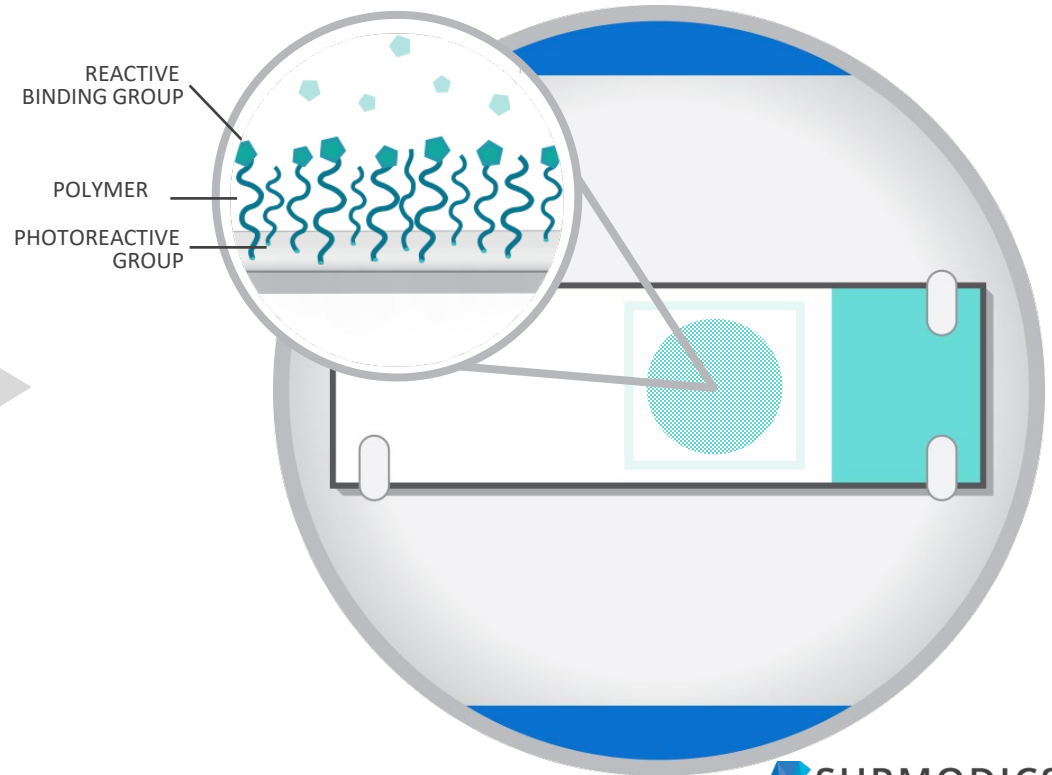
COLORIMETRIC SUBSTRATES

# MOLECULAR DIAGNOSTICS

## MICROARRAY SLIDES / SURFACE CHEMISTRY

TRIDIA™ (formally CodeLink®) slides, coatings immobilize biological entities to surface materials

- Reactive chemistries allow for use in molecular or protein applications
- Passivating polymer increases sensitivity by preventing non-specific binding of unwanted biomolecules
- Thin, versatile photochemistry allows coating of various geometries and surface materials

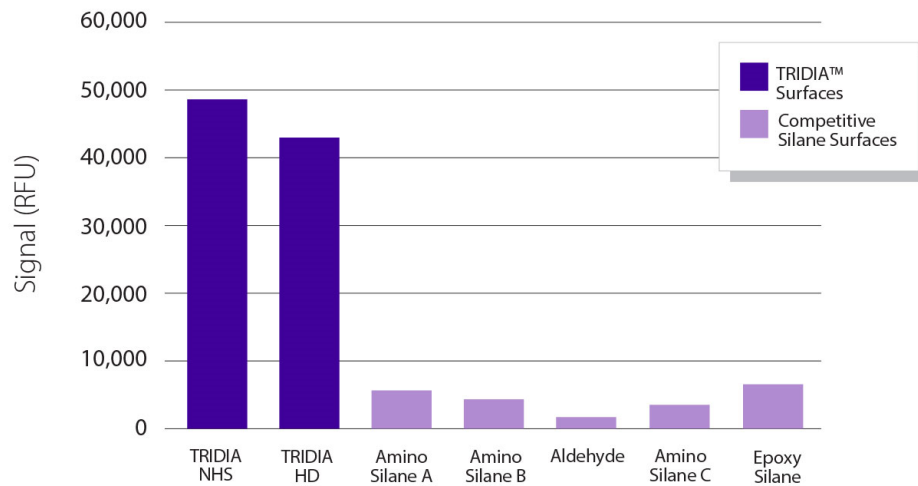


# MICROARRAY SLIDES / SURFACE CHEMISTRY

## TRIDIA™ microarray slides and surfaces offer:

- Superior binding compared to other microarray surfaces
  - NHS ester amine-reactive groups for DNA/RNA applications
  - Epoxide and streptavidin groups for protein applications
- Various hydrophobic surface coating to match your applications
- Passivating polymer to ensure low background

## DNA OLIGONUCLEOTIDE BINDING TO MICROARRAY SLIDE SURFACES



# THANK YOU

[www.surmodics.com](http://www.surmodics.com)

[shop.surmodics.com](http://shop.surmodics.com)

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